DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 21, 2014

OSSTEM Implant Company, Limited
C/O Mr. Patrick Lim
Manager
HIOSSEN Incorporated
85 Ben Fairless Drive
Fairless Hills, PA 19030

Re: K140600
Trade/Device Name: SB Anchor
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: June 23, 2014
Received: July 10, 2014

Dear Mr. Lim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use Statement

Indications for Use

510(k) Number K 140600

Device Name : SB Anchor

Indication for use : SMARTbuilder System is a metal (Non-resorbable membrane) device intended for use with a dental implant to stabilize and support of bone graft in dento-alveolar bony defect sites.

Prescription Use X (Per 21CFR801 Subpart D) OR Over-The-Counter Use _____. (Per 21CFR807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: February 21, 2014

1. Company and Correspondent making the submission:

- Submitter's Name :	OSSTEM Implant Co., Ltd.
- Address :	203, Geoje-daero, Yeonje-Gu Busan, 611-804, Republic of Korea
- Contact :	Mr. Hee Kwon Son
- Phone:	+82 51 850 2575
- Correspondent's Name:	HIOSSEN Inc.
- Address:	85 Ben Fairless Dr. Fairless Hills, PA 19030
- Contact:	Patrick Lim
- Phone:	888 678 0001

2. Device :

Trade or (Proprietary) Name :	SB Anchor
Common or usual name :	Dental Abutment
Classification Name :	Endosseous dental implant abutment 21CFR872.3630 Class Ⅱ NHA

3. Predicate Device :
SMARTbuilder System, OSSTEM IMPLANT CO.,LTD (K120951)

4. Description :

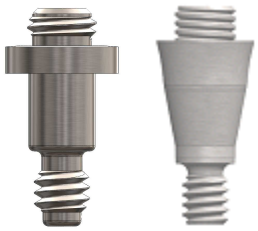
SB Anchor is used for connecting with Healing abutment or Cover Cap on the top of the SB Anchor to fix the SMARTbuilder that is predicated 510(K), K120951, K130840

The SB Anchor has the same material, indication for use, technological characteristics and similar design as the predicate device, Height in the SMARTbuilder System

The SB Anchor is designed for use with NT Fixture connection (K081078) and TS SA Fixture connection (K121995)

Material	Titanium alloy Ti-6Al-4V (ASTM F 136)	Compatible connection / Dimension	NT Fixture Connection	Diameter : 3.5, 4.0, 5.0 Length: 6.35 ~ 9.85
			TS SA Fixture Connection	Diameter : 3.3, 3.7, 4.2, 4.25, 4.4, 4.6, 4.63, 4.65, 4.9, 5.05, 5.08, 5.1 Length: 7.0~ 15
surface treatments	none	Method of Sterilization		Radiation (Gamma)

- Substantial Equivalence Matrix

	SB Anchor		SMARTbuilder System Height
510(k)	Proposed		K120951
Manufacturer	OSSTEM Implant Co., Ltd.	OSSTEM Implant Co., Ltd.	OSSTEM Implant Co., Ltd.
Design			
Compatible Fixture	NT Fixture (K081078)	TS SA Fixture (K121995)	GS III System (K091208)
Indication for use	SMARTbuilder System is a metal (Non-resorbable membrane) device intended for use with a dental implant to stabilize and support of bone graft in dento-alveolar bony defect sites.	SMARTbuilder System is a metal (Non-resorbable membrane) device intended for use with a dental implant to stabilize and support of bone graft in dento-alveolar bony defect sites.	SMARTbuilder is a metal device intended for use with a dental implant to stabilize and support of bone graft in dento-alveolar bony defect sites.
Material	Titanium alloy Ti-6Al-4V (ASTM F 136)	Titanium alloy Ti-6Al-4V (ASTM F 136)	Titanium alloy Ti-6Al-4V (ASTM F 136)
Dimension	Diameter : 3.5, 4.0, 5.0 Length: 6.35 ~ 9.85	Diameter : 3.3, 3.7, 4.2, 4.25, 4.4, 4.6, 4.63, 4.65, 4.9, 5.05, 5.08, 5.1 Length: 7.0~ 15	Diameter : 3.3, 4 Length: 7.15 ~ 9.85
surface treatments	None	None	None
Sterilization	Sterilie	Sterilie	Sterilie
Shelf life	8years	8years	8years
S E	The SB Anchor has the same material, indication for use, technological characteristics and similar design as the predicate device, Height in the SMARTbuilder System Product name is changed SMARTbuilder System, Height to SB Anchor and addition various anchor shape products to apply various connection structure		

5. Indication for use
SMARTbuilder System is a metal (Non-resorbable membrane) device intended for use with a dental implant to stabilize and support of bone graft in dento-alveolar bony defect sites.

6. Review :

The SB Anchor has the same material, intended for use and technological characteristics as the predicate device.

7. Summary of nonclinical testing

Biocompatibility evaluation for SB Anchor is not considered because material of SB Anchor is same with Height of SMARTbuilder System(K120951)

8. Summary of clinical testing
No clinical studies are submitted

9. Conclusions
In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807**,** and based on the information provided in this premarket notification Osstem Implant Co., Ltd. concludes that the SB Anchor is substantially equivalent to the predicate devices as described herein.